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November 7, 2011

Azadeh Mohandessi-Fares, CalOHII
1600 9th Street, Room 460 - MS 20-10
Sacramento, CA 95814

Re: Cal eConnect Comments to Cal OHII's revised Draft HIE Demonstration Project
Regulations authorized by 2010 AB 278

Dear Ms. Mohandessi-Fares:

Cal eConnect welcomes this opportunity to provide comments on Cal OHII's revised 'HIE Demonstration Project Proposed Regulations'. Cal eConnect provided comment to the original proposed regulations and as we reviewed these revisions we are happy to see the positive changes.

As the State Governance Entity, we too are interested in enabling health information exchange to "significantly improve the quality of treatment and care, reduce unnecessary health care costs, and increase administrative efficiencies within the health care system". We are concerned that there are some specific items remaining in the revised draft that will create confusion and as a result prevent the exchange of data.

In total, we believe that the State's intent in drafting these conservative proposed regulations is to establish a baseline against which the process of demonstrating alternative requirements can be documented. An unintentional consequence of this approach is that many stakeholders have understood this conservative baseline to be the State's position regarding what is necessary to protect the privacy of consumers. This unintended consequence has unfortunately resulted in a complete lack of interest on the part of HIE implementers to demonstrate the alternative methods of ensuring security and privacy that are employed by so many successful exchanges across the Nation.

We are confident that the State is committed to working with the stakeholders who are committed to ubiquitous and robust health information exchange in California. We provide the following comments as we believe they are necessary to ensuring the success of this pivotal program.

Improvements in Clarity and Scope in the current iteration

Cal eConnect applauds the numerous updates that improve the clarity found in these revisions. We especially noted the adoption of HIPAA in the definitions section and the careful delineation made in electing CMIA terms where differences between the use of HIPAA and State terms are important.



Further, we find the revisions to security sections (§126070, §126072, §126074, §126076) to be particularly demonstrative of the State's responsiveness to public comments to the original draft. We found specifically referring to the HIPAA security standards in Subpart C of Part 164, 45 C.F.R. §164.302 and the replacement of directives on how with objectives to be important improvements.

The clarification limiting the scope of demonstration projects to exchange amongst unaffiliated entities goes a long way in aiding potential Applicant's in understanding how their participation in the Program will be instrumental to advancing the maturation of health information exchange in the State of California.

Recommendations to the Revised Draft HIE Regulations

§126020 Definitions

We question whether "EHR Vendor Agreement" is, actually, the intended document requested. Most HIO-facilitated exchange is done through a middleware solution, and is generally provided by "HIE Vendors". Therefore, it would seem, that the document most likely to be requested would be the HIE Vendor Agreement – see our comments on §126040(b)(2))

§126040 Transparency and Complaint Process

It seems that the question at hand is who will have access to the data disclosed through the Health Information Organizations (HIO) facilitated exchange. Since HIOs are listed as potential participants, and participation agreements generally delineate the scope of allowable access and use of the data, the list of an HIO's Participant's (end users) along with the data participation agreement should provide the State with this information. We recommend this section read like this:

§126040(b)(1) Information on parties to the IHI

- (a) If the Participant is a HIO: a list of everyone who has signed the HIO's exchange agreement (this could be a data participation agreement, a BAA, or other form of agreement), with their contact information and a general description of the service(s) provided, including the data shared, the purpose, and whether further dissemination of the data is allowed, regardless of whether the information is de-identified. This requirement may be modified to reflect only those business associates and trading partners with access to the individual health information exchanged through the demonstration project.
- (b) If the Participant is not an HIO: a list of all of the Participant's current business associates and trading partners with electronic access to the individual health information disclosed through the demonstration project, with their contact information and a general description of the service(s) provided, including the data shared, the purpose, and whether further dissemination of the data is allowed, regardless of whether the information is de-identified. This requirement may be modified to reflect only those



business associates and trading partners with access to the individual health information exchanged through the demonstration project.

- (c) In either case, if a new business associate or trading partner is added after the start of the project, or a business associate agreement or trading partner agreement is modified, the Participant must provide CalOHII with an updated list quarterly within 20 business days of the commencement of the business associate agreement or data exchange partner agreement or the provision of services, whichever is earlier.
- (d) In CalOHII's discretion, CalOHII may require copies of the Participant's business associate agreements and trading partner agreements. The Participant shall provide copies within five working days from the receipt of written request from CalOHII.

With regards to §126040(b)(2) "A copy of the EHR Vendor agreement for each Participant" – It should be noted that "Participant" is currently defined as the organization that is testing the proposed regulations – that is, the named Demonstration Project organization. As such, the Participant does not typically have an "EHR Vendor Agreement" but is most likely to have an "HIE Vendor Agreement."

It appears to us that the continued requirement to collect Participant's business associates agreements and the new requirement to collect the Participant's 'EHR Vendor Agreement' is the State's attempt to collect information about secondary use of clinical information at the edge systems involved in information exchange. From our perspective, attempting to overload the requirements of this Program with an analysis of the EHR agreements is out of scope in a program designed to support health information exchange.

If the intention of this item is to retrieve information on EHR vendor agreements, we respectfully suggest this is an inappropriate burden on HIOs whose work is focused on HIE. We recommend that CalOHII work with the Regional Extension Centers to get a copy of the negotiated agreements, and with CHA and/or the UC system to get a representative sample of Acute Care EHR agreements (Meditech, Epic, Cerner, Allscripts Sunrise, etc.)

This single item is likely to keep organizations from participating with HIOs that want to be Demonstration projects.

§126052 Trade Secret Designation and Protection

We respectfully request that Cal OHII consider in the Request for Confidentiality a "Pre-approval" process. This will allow for a determination of the confidentiality before the data is in a Public Agency's hands, and fully protects the information from disclosure.

§126050 Permitted Purposes for Exchanging Health Information

We recommend that CalOHII clarify the scope of the State's requirements regarding an HIO Applicant's requests to develop alternative requirements for additional purposes of use. In §126050 the state identifies four permitted purposes for exchange through an HIO. We understand that for Applicant's that have the capacities to demonstrate other purposes not



included in these permitted purposes that §126060.(a) of the draft regulations allows the Applicant to request CalOHII to develop an alternative requirement for the Applicant's demonstration project.

We believe that there will be instances where Applicant's will have the capacity to demonstrate more than one alternative purpose of use. Where we seek clarification is related to the mixed case where the State approves the demonstration of one but not all alternative purposes proposed by an Applicant.

An example may help illustrate the scenario. Consider the case of an operational HIO currently enabling a number of exchanges that satisfy real world requirements that are outside the scope of the four permitted purposes supported in §126050. This applicant elects to submit two requests to demonstrate alternative requirements. The first request is related to an alternative purpose that CalOHII grants a request for while the second request does not receive this approval.

From the perspective of the Applicant's ongoing operations do the draft regulations in any way force the discontinuation of the alternative purpose(s) not approved by CalOHII? Put another way – is there a requirement that an Applicant, upon becoming a Demonstration Project participant, only operate services that are either covered by the four permitted purposes indicated in §126050 or those others that were permitted via the Request to Demonstrate Alternative Requirements process?

§126055 Informing Requirements; Affirmative Consent; Revocation of Consent

Section 126050 details conservative requirements related to consent processes with a significant portion of the requirements being placed on the front-line providers of care. Further it is implied that the proposed consent requirements apply equally to all permitted purposes of use. We believe there should be clarification for each previously-permitted purpose.

§126060 Requests to Develop Alternative Requirements

We are especially pleased that this draft expands on the waiver process. We believe that the general factors listed in section (b).1 will be consistently described in Applicant's Request to Develop Alternative Requirements and that the limitations given in section (b).2.a echoes the understanding of likely Applicant's that the operations of HIO must be consistent with current applicable law.

We fully appreciate that Cal OHII has limited staff and must prioritize its work, but January, 2014, which is the official end of the HIE State Cooperative Agreement, is approaching quickly. Due to the limited time, we believe that §126060(c) must remove "a reasonable time frame" and replace it with either "45 days" or "30 days with no more than one 30 day extension."

Clarifying the utility of the Request to Develop Alternative Requirements



From a policy development perspective we recognize that the State is using a conservative approach to defining the baseline requirements and have implemented a process whereby Applicants would document how their pilot approach would differ from these baseline conservative requirements to reflect in-field practical solutions that are implementable in today's environment.

Based on the feedback that we have gotten from the community including the HIE leadership of our Board, Advisory Groups and Expansion Grantees there is a lack of understanding among potential Applicants and those analyzing the proposed regulations about the intention of the State to use the waiver-like approach to facilitate the process of enabling pilots that operate using alternative requirements. There is not only a lack of appreciation for this by many in the public, but there is a significant cohort of interested stakeholders that see the proposed regulations as the State's desired end-point rather than as a reference framework to be used in informing the development of regulations in the future.

Cal eConnect's recommendation to the State would be to implement a communication solution to address these misconceptions. We interpret these draft regulations to be a tool to enable discovery of what is possible. They will constrain future learning about what alternatives are satisfactory or exceed the protections modeled by the conservative regulatory framework described.

We think that it may be especially helpful to those parties likely to apply to be a demonstration project to hear from the State about the Projects that have been approved and about the projects that would be especially informative to this learning process. Cal eConnect would be happy to support this kind of forum or outreach and invite the opportunity to support CalOHIE in this way.

The State indicates that the inclusion of §126030 "California Health Information Exchange Practices Principles" is to provide guidance to those Applicants that are proposing alternatives to the proposed regulations. Please consider developing an educational session for Applicants to facilitate a clearer understanding about the relationship between the draft regulations and the Principles. That would significantly improve their ability to write 'Request to Develop Alternative Requirements' in a way conducive to the States approval of such applications.

An opportunity to further clarify scope of demonstration projects

The State takes efforts to define the concept of a conduit mode of exchange in the revisions. In the context of limiting the scope and purpose of the demonstration projects we encourage the State in a subsequent draft of these Regulations to treat conduit modes of exchange (which do not rise to the level of requiring a BAA under HIPAA) as being outside the scope of these projects. We believe that, just as excluding demonstrations of intra-affiliated exchange, excluding Independent Directed Exchange from the scope of these demonstration projects will further focus the scope of this program on the types of exchange that were intended to be included by the authorizing legislation.

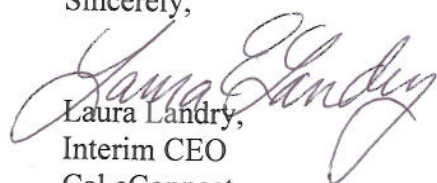


Ultimately, a global statement of purpose that clearly defines the scope of unaffiliated exchange (this is not about exchange amongst affiliates nor via modes of exchange where access to unencrypted PHI is limited to treating physicians) to be performed under this program and the intent of the State to capitalize on proven alternative requirements in drafting future more broadly applicable regulation may address many concerns being voiced by others in the community.

In Summary

We congratulate the State in its responsiveness to the first round of commenting. The improvements in this major revision have clarified the direction and intent of the State. We strongly support CalOHII continuing to refine definitions and scope in order to allow for incremental changes that advance progress in achieving the vision of safe and secure HIE for all Californians.

Sincerely,


Laura Landry,
Interim CEO
Cal eConnect